



House of Representatives

General Assembly

File No. 268

January Session, 2011

House Bill No. 5610

House of Representatives, March 29, 2011

The Committee on Public Health reported through REP. RITTER, E. of the 38th Dist., Chairperson of the Committee on the part of the House, that the bill ought to pass.

AN ACT CONCERNING THE DUTIES OF A PHARMACIST WHEN FILLING A PRESCRIPTION USED FOR THE TREATMENT OF EPILEPSY OR PREVENTION OF SEIZURES.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

1 Section 1. Section 20-619 of the general statutes is repealed and the
2 following is substituted in lieu thereof (*Effective October 1, 2011*):

3 (a) For the purposes of section 20-579 and this section:

4 (1) "Brand name" means the proprietary or trade name selected by
5 the manufacturer and placed upon a drug product, its container, label
6 or wrapping at the time of packaging;

7 (2) "Generic name" means the established name designated in the
8 official United States [Pharmacopoeia/National Formulary]
9 Pharmacopoeia-National Formulary, official Homeopathic
10 Pharmacopoeia of the United States, or official United States [adopted
11 names] Adopted Names or any supplement to any of [them] said
12 publications;

13 (3) "Therapeutically equivalent" means drug products that are
14 approved under the provisions of the federal Food, Drug and
15 [Cosmetics] Cosmetic Act for interstate distribution and that will
16 provide essentially the same efficacy and toxicity when administered
17 to an individual in the same dosage regimen; [and]

18 (4) "Dosage form" means the physical formulation or medium in
19 which the product is intended, manufactured and made available for
20 use, including, but not limited to, tablets, capsules, oral solutions,
21 aerosol, inhalers, gels, lotions, creams, ointments, transdermals and
22 suppositories, and the particular form of any physical formulation or
23 medium that uses a specific technology or mechanism to control,
24 enhance or direct the release, targeting, systemic absorption, or other
25 delivery of a dosage regimen in the body;

26 (5) "Epilepsy" means a neurological condition characterized by
27 recurrent seizures;

28 (6) "Seizures" means a disturbance in the electrical activity of the
29 brain; and

30 (7) "Antiepileptic drug" means a drug prescribed for the treatment
31 of epilepsy or a drug used to prevent seizures.

32 (b) Except as limited by subsections (c), [and] (e) and (i) of this
33 section, unless the purchaser instructs otherwise, the pharmacist may
34 substitute a generic drug product with the same strength, quantity,
35 dose and dosage form as the prescribed drug product which is, in the
36 pharmacist's professional opinion, therapeutically equivalent. When
37 the prescribing practitioner is not reasonably available for consultation
38 and the prescribed drug does not use a unique delivery system
39 technology, the pharmacist may substitute an oral tablet, capsule or
40 liquid form of the prescribed drug as long as the form dispensed has
41 the same strength, dose and dose schedule and is therapeutically
42 equivalent to the drug prescribed. The pharmacist shall inform the
43 patient or a representative of the patient, and the practitioner of the
44 substitution at the earliest reasonable time.

45 (c) A prescribing practitioner may specify in writing or by a
46 telephonic or other electronic communication that there shall be no
47 substitution for the specified brand name drug product in any
48 prescription, provided (1) in any prescription for a Medicaid, state-
49 administered general assistance, or ConnPACE recipient, such
50 practitioner specifies the basis on which the brand name drug product
51 and dosage form is medically necessary in comparison to a chemically
52 equivalent generic name drug product substitution, and (2) the phrase
53 "BRAND MEDICALLY NECESSARY", shall be in the practitioner's
54 handwriting on the prescription form or on an electronically-produced
55 copy of the prescription form or, if the prohibition was communicated
56 by telephonic or other electronic communication that did not
57 reproduce the practitioner's handwriting, a statement to that effect
58 appears on the form. The phrase "BRAND MEDICALLY NECESSARY"
59 shall not be preprinted or stamped or initialed on the form. If the
60 practitioner specifies by telephonic or other electronic communication
61 that did not reproduce the practitioner's handwriting that there shall
62 be no substitution for the specified brand name drug product in any
63 prescription for a Medicaid, state-administered general assistance, or
64 ConnPACE recipient, written certification in the practitioner's
65 handwriting bearing the phrase "BRAND MEDICALLY NECESSARY"
66 shall be sent to the dispensing pharmacy [within] not later than ten
67 days after the date of such communication.

68 (d) Each pharmacy shall post a sign in a location easily seen by
69 patrons at the counter where prescriptions are dispensed stating that,
70 "THIS PHARMACY MAY BE ABLE TO SUBSTITUTE A LESS
71 EXPENSIVE DRUG PRODUCT WHICH IS THERAPEUTICALLY
72 EQUIVALENT TO THE ONE PRESCRIBED BY YOUR DOCTOR
73 UNLESS YOU DO NOT APPROVE." The printing on the sign shall be
74 in block letters not less than one inch in height.

75 (e) A pharmacist may substitute a drug product under subsection
76 (b) of this section only when there will be a savings in cost passed on
77 to the purchaser. The pharmacist shall disclose the amount of the
78 savings at the request of the patient.

79 (f) Except as provided in subsection (g) of this section, when a
80 pharmacist dispenses a substitute drug product as authorized by
81 subsection (b) of this section, the pharmacist shall label the
82 prescription container with the name of the dispensed drug product. If
83 the dispensed drug product does not have a brand name, the
84 prescription label shall indicate the generic name of the drug product
85 dispensed along with the name of the drug manufacturer or
86 distributor.

87 (g) A prescription dispensed by a pharmacist shall bear upon the
88 label the name of the drug in the container unless the prescribing
89 practitioner writes "DO NOT LABEL", or words of similar import, on
90 the prescription or so designates in an oral or electronic transmission
91 of the prescription.

92 (h) Neither the failure to instruct by the purchaser as provided in
93 subsection (b) of this section nor the fact that a sign has been posted as
94 provided in subsection (d) of this section shall be a defense on the part
95 of a pharmacist against a suit brought by any such purchaser.

96 (i) Upon the initial filling or renewal of a prescription that contains a
97 statistical information code based upon the most recent edition of the
98 International Classification of Diseases indicating the prescribed drug
99 is used for the treatment of epilepsy or to prevent seizures, a
100 pharmacist shall not: (1) Substitute for the prescribed drug another
101 antiepileptic drug or formulation of another antiepileptic drug,
102 irrespective of whether such other antiepileptic drug is a brand name
103 drug product or a generic name drug product, or (2) fill the
104 prescription by using a different drug manufacturer or distributor of
105 the prescribed drug, unless the pharmacist provides prior notice of
106 such substitution or use of a different drug manufacturer or distributor
107 to, and obtains the written consent of, the patient's prescribing
108 practitioner. For purposes of obtaining the consent of the patient's
109 prescribing practitioner required by this subsection, a pharmacist shall
110 notify the prescribing practitioner via electronic mail or facsimile
111 transmission. If the prescribing practitioner does not provide the

112 necessary consent, the pharmacist shall fill the prescription without
 113 such substitution or use of a different drug manufacturer or distributor
 114 or return the prescription to the patient or to the patient's
 115 representative for filling at another pharmacy. If a pharmacist is
 116 unable to contact the patient's prescribing practitioner after making
 117 reasonable efforts to do so, such pharmacist may exercise professional
 118 judgment in refilling a prescription in accordance with the provisions
 119 of subsection (b) of section 20-616. For purposes of this subsection,
 120 "pharmacy" means a place of business where drugs and devices may
 121 be sold at retail and for which a pharmacy license was issued pursuant
 122 to section 20-594, including a hospital-based pharmacy when such
 123 pharmacy is filling prescriptions for employees and outpatient care,
 124 and a mail order pharmacy licensed by this state to distribute in this
 125 state. "Pharmacy" does not include a pharmacy serving patients in a
 126 long-term care facility, other institutional facility or a pharmacy that
 127 provides prescriptions for inpatient hospitals.

128 [(i)] (j) The commissioner, with the advice and assistance of the
 129 commission, shall adopt regulations, in accordance with chapter 54, to
 130 carry out the provisions of this section.

131 Sec. 2. Section 17b-493 of the general statutes is repealed and the
 132 following is substituted in lieu thereof (*Effective October 1, 2011*):

133 A pharmacist shall, except as limited by [subsection (c)] subsections
 134 (c), (e) and (i) of section 20-619, as amended by this act, and section
 135 17b-274, substitute a therapeutically and chemically equivalent generic
 136 drug product for a prescribed drug product when filling a prescription
 137 for an eligible person under the program.

This act shall take effect as follows and shall amend the following sections:		
Section 1	<i>October 1, 2011</i>	20-619
Sec. 2	<i>October 1, 2011</i>	17b-493

PH *Joint Favorable*

The following Fiscal Impact Statement and Bill Analysis are prepared for the benefit of the members of the General Assembly, solely for purposes of information, summarization and explanation and do not represent the intent of the General Assembly or either chamber thereof for any purpose. In general, fiscal impacts are based upon a variety of informational sources, including the analyst's professional knowledge. Whenever applicable, agency data is consulted as part of the analysis, however final products do not necessarily reflect an assessment from any specific department.

OFA Fiscal Note

State Impact:

Agency Affected	Fund-Effect	FY 12 \$	FY 13 \$
Comptroller Misc. Accounts (Fringe Benefits); Social Services, Dept.	GF and TF - Potential Cost	See Below	See Below

Municipal Impact:

Municipalities	Effect	FY 12 \$	FY 13 \$
Various Municipalities	STATE MANDATE - Potential Cost	See Below	See Below

Explanation

There may be a cost to the state employee health plan to the extent that the provisions of the bill conflict with the generic substitution requirement implemented in accordance with the 2009 agreement reached between the State and the State Bargaining Agency Coalition (SEBAC). The bill would disallow generic substitution unless expressly stated by the prescribing physician for epilepsy or seizure drugs. To the extent that the prescribed drug is more expensive than the equivalent generic, there would be increased costs to the state employee health plan. The number of prescriptions per year that would be prescribed contrary to the generic substitution is not known. In addition, any plan changes required to conform to the bill's provisions would require collective bargaining agreement.

The bill's provisions may increase costs to certain municipal plans that currently require generic substitutions requirements similar to the state employee health plan.

The bill could result in a cost to the Department of Social Services (DSS) associated with increased pharmaceutical costs. The provisions of this bill appear to conflict with the department's preferred drug list program. Under this program, DSS clients are dispensed only drugs that are on the department's approved list if that list contains a drug that is therapeutically equivalent to the prescribed drug. This bill would disallow this practice for epilepsy or seizure drugs. To the extent that the prescribed drug is more expensive than the equivalent on the preferred drug list, DSS would incur increased costs under Medicaid and CONNPACE. The number of prescriptions per year that would be removed from the preferred drug list due to this bill is not known. Overall, DSS spends approximately \$400 million annually on pharmaceuticals.

The Out Years

The annualized ongoing fiscal impact identified above would continue into the future subject to inflation.

OLR Bill Analysis**HB 5610*****AN ACT CONCERNING THE DUTIES OF A PHARMACIST WHEN FILLING A PRESCRIPTION USED FOR THE TREATMENT OF EPILEPSY OR PREVENTION OF SEIZURES.*****SUMMARY:**

This bill prohibits retail pharmacists from substituting any alternative for a drug prescribed to treat epilepsy or prevent seizures without the prior written approval of the prescribing practitioner. The law already permits a prescriber to tell a pharmacist not to substitute a generic name drug for any brand name one.

EFFECTIVE DATE: October 1, 2011

BANNING SUBSTITUTIONS FOR ANTI-EPILEPTIC DRUGS

The bill bans certain pharmacists, without the prescriber's written consent, from (1) substituting another brand name or generic name drug product or drug formulation for the prescribed drug or (2) filling the prescription with a product from a different manufacturer or distributor. It applies to new and renewal prescriptions that contain an International Classification of Diseases statistical code indicating the drug is used to treat epilepsy or prevent seizures.

The ban applies to community pharmacies, hospital pharmacies that serve employees and outpatients, and mail order pharmacies licensed to distribute drugs in Connecticut. It does not apply to pharmacies (1) in long-term care facilities, such as nursing homes, chronic disease hospitals, and intermediate care facilities for people with mental retardation; (2) serving hospital in-patients; and (3) in other institutions.

The bill requires the pharmacist to notify the prescriber by email or fax to obtain consent. If the prescriber does not consent, the pharmacist

must fill the prescription without substitution or return it to the patient or his or her representative for filling at another pharmacy.

If, after making reasonable efforts, a pharmacist cannot contact the prescriber, he or she may refill a prescription with a 72-hour supply if, in his or her professional judgment, failure to do so might interrupt the patient's therapeutic regimen or cause the patient to suffer. When dispensing the refill, the pharmacist must tell the patient or the patient's representative that the prescriber did not authorize it and inform the prescriber that he or she must authorize future refills. The pharmacist may refill a prescription this way just once.

BACKGROUND

Drug Substitution

Under existing law, which the bill does not change, a prescriber may tell a pharmacist not to substitute a generic name for any brand name drug. The prescriber must do this by writing "Brand Medically Necessary" on the prescription form or, if the prescriber calls in the prescription or electronically transmits it in a way that does not reproduce his or her handwriting, by stating so on the communication. For Medicaid, State-Assisted General Assistance, and ConnPACE clients, the prescriber must (1) specify why the name brand and dosage are medically necessary and (2) send the "brand medically necessary" certification to the pharmacist in writing within 10 days if it was not on the prescription form. This law applies to all pharmacies.

COMMITTEE ACTION

Public Health Committee

Joint Favorable

Yea 26 Nay 0 (03/14/2011)